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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/666,778

09/18/2003

Alain Goossens

2676-6085US

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24247 7590 02/14/2007
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EXAMINER

KALLIS, RUSSELL

ART UNIT

PAPER NUMBER

1638

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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3 MONTHS

02/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/666,778

Applicant(s)

GOOSSENS ET AL.

Examiner

Russell Kallis

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim 14 is cancelled. Claims 1-13 and 15-19 are pending and examined.

Rejection of Claim 15 under 35 U.S.C. 112, first paragraph is withdrawn in view of Applicants amendments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Dudler R. *et al.* Journal of Biological Chemistry; 25 March 1992, Vol. 267, No. 9 pp. 5582-5888.

Dudler teaches an atg start codon on page 5884 in column 1 that meets the limitation of a polynucleotide sequence of SEQ ID NO: 1; wherein the claim limitation ‘a polynucleotide sequence of SEQ ID NO: 1’ is interpreted as any polynucleotide sequence of SEQ ID NO: 1.

Amending the claim to recite ‘the polynucleotide sequence of SEQ ID NO: 1’ would obviate this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1638

Claims 1-13 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theodoulou F. *Biochemica et Biophysica Acta*; 2000, 1465, pp. 79-103 in view of Dudler R. *et al.* *Journal of Biological Chemistry*; 25 March 1992, Vol. 267, No. 9 pp. 5582-5888. This rejection is maintained for the reasons of record set forth in the Official action mailed 8/11/2006. Applicant's arguments filed 11/13/2006 have been considered but are not deemed persuasive.

Applicant asserts that there is no single straightforward suggestion in Theodoulou *et al.* to motivate one of ordinary skill in the art to use ABC transporter proteins to increase the yield of secondary metabolites in plants and that the combination of Theodoulou and Dudler would require hindsight reasoning.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., function or substrate specificity) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, Theodoulou points directly to screening for alkaloids.

The claims are broadly drawn to processes of enhancing secretion of a plant secondary compound by transforming a plant or plant cell with a vector comprising a gene encoding an ABC-transporter; and plants and plant cells thereof.

Theodoulou teaches ABC transporter genes from plants that have strong similarity to MDR proteins from other species and suggests a role of the plant homologues in the secretion or sequestering of *vinca* alkaloid and the alkaloid taxol and suggests a strategy for screening transformed plants and plant cells for determining the specific transport function (section 5.2 page 86).

Dudler teaches an MDR like gene from Arabidopsis and transformation therewith (See Abstract and column 1 page 5888 lines 40-53).

It would have been obvious at the time of Applicant's filing to take a plant ABC transporter gene that encoded a protein that had similar structural motifs to the human MRD ABC transporter and test for induced or enhanced production or secretion of an alkaloid such as the *vinca* alkaloid or taxol to determine the function of the plant MDR homologue. One of ordinary skill in the art would have been motivated by the teaching of Theodoulou that taxol and other plant secondary metabolites are substrates or bind MDR ABC transporter proteins and would be useful in the art of bioengineering secondary product production in plants or plant cells that produce taxol, *vinca* alkaloid or other plant secondary compounds; and have had a reasonable expectation of success given that transgenic strategies for evaluating the specific function of plant ABC transporter genes were within the reach of one of ordinary skill and that non-plant alkaloid transporters and methods of transforming plants and maintaining plant cell cultures for the production of secondary metabolites were known in the art.

Application/Control Number: 10/666,778

Page 5

Art Unit: 1638

Claims 1-13 and 15-19 are rejected.

Art Unit: 1638

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Russell Kallis Ph.D.
February 4, 2007

RUSSELL P. KALLIS, PH.D.
PRIMARY EXAMINER

A handwritten signature in cursive script that reads "Russell Kallis".